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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/726,024	12/02/2003	Manesh Dixit	141-239A	2662

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EXAMINER	
CLAYTOR, DEIRDRE RENEE	
ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 10/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/726,024	DIXIT ET AL.	
	Examiner	Art Unit	
	Renee Claytor	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 December 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *3/1/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Priority

This application claims priority to U.S. Provisional Application 60/431,954. Applicant's priority is acknowledged.

Claim Rejections – 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 27 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear what the plasma peaks and troughs of the delivered active ingredient similar to those experienced in multiple dosing regimens are referring to. What are the plasma peaks and troughs experienced in multiple dosing regimens?

Claim Rejections – 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ting et al. (U.S. Patent 6,372,254) in view of Mehta et al. (U.S. Patent 5,837,284).

Mehta et al. teach an improved dosing of methylphenidate hydrochloride, in an amount from about 2% to about 99% by weight, whereby two time-separated doses are provided via a single dosage unit (meeting the limitation of claims 1 and 21-22; (Col. 1, lines 13-17, Vol. 4, lines 54-58). The dosage unit is comprised of talc (meeting the limitation of claim 14-15), polyethylene glycol, and citrates (meeting the limitations of claims 12-13), methacrylic acid (meeting the limitation of claims 10-11 and 24; Col. 7, lines 20-32), and hydroxypropyl methylcellulose (meeting the limitations of claims 5-7 and 16; Col. 10, lines 42-50). Mehta et al. further teach that the maximum concentration of the first dose occurs from about 1 hour to about 3 hours after ingestion, which is followed by a period when no drug is released which lasts approximately 2-6 hours, and the second dose is released about 6 hours following administration (meeting the limitation of claims 27-29, Col. 5, lines 37-51 and Fig. 2).

Mehta et al. does not teach a diluent, anti-sticking agents (enumerated in claims 8-9), peak blood plasma levels in the immediate release and extended release portions, a maximum plasma concentration up to about 20 ng/ml, an AUC_{0-24} up to about 200 ng/ml, and plasma peaks and troughs of the delivered active ingredient similar to those experienced in multiple dosing regimens.

Ting et al. teach a drug delivery system that facilitates a pulsatile release of a drug (with methylphenidate being listed as a drug that can be used in this system; meeting the limitation of claims 1-2, 23; Col. 4, line 61 and claim 9). The drug delivery system contains an immediate-release compartment surrounded by an extended-release compartment (encompassing the limitations of claims 1, 21-22; Col. 2, lines 46-

57). The extended release compartment of the prior art may be comprised of colloidal silicon dioxide and magnesium stearate (meeting the limitation of claim 8-9, 14), lactose (meeting the limitation of claims 3-4; Table 2), and zein (further meeting the limitations of claims 10-11 and 24; Col. 4, line 67). Ting et al. also teach that the drug-delivery system is delivered in a single orally administrable tablet that provides a first order delivery of the active agent between 1 and 5 hours and after 6 hours the rest of the drug is released (meeting the limitations of claims 17 and 18, Col. 4).

Furthermore, it is obvious to vary and/or optimize the weight of each ingredient in the controlled release formulation, a maximum plasma concentration, and an AUC, according to the guidance provided by Ting et al. and Mehta et al., to ensure that the proper amount of drug is released at the designated time interval. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

Accordingly, it would have been obvious to one having ordinary skill in the art at the time the invention was made to combine the teachings of Mehta et al. which teach a composition for the improved dosing of methylphenidate, with Ting et al. which teach a drug delivery system that facilitates the pulsatile release of a drug, including methylphenidate. One having ordinary skill in the art would have been motivated to combine the teachings of Mehta et al. and Ting et al. to formulate delayed release compositions of methylphenidate to reduce abuse potential and for better patient compliance to treat nervous system disorders.

Conclusion

No claims are allowed.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Renee Claytor whose telephone number is 571-272-8394. The examiner can normally be reached on M-F 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Renee Claytor

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER